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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,104	08/17/2000	Walter Birchmeier	105357-427-NP	5225
23557	7590	11/18/2004	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,104

Applicant(s)

BIRCHMEIER ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44,45,47,48 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44,45,47,48 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of the Claims

1. Claims 44, 45, 47, 48 and 50 are pending.

Applicant's amendment filed September 7, 2004 is acknowledged. Applicant's response has been fully considered. Claims 44, 45 and 47 have been amended, and claims 46 and 49 have been cancelled. Thus, claims 44, 45, 47, 48 and 50 and SEQ ID NOs: 6, 7, 8, 9, 10, 11 and 12 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 44-50 under 35 USC § 112, first paragraph, is withdrawn in view of applicants' amendment to the claim, applicant's cancellation of the claim, and applicant's response at page 5 of the amendments filed September 7, 2004.
3. The previous rejection of claims 46 and 49 under 35 USC § 112, second paragraph, is withdrawn in view of applicant's cancellation of the claim, and applicant's response at page 5 of the amendments filed September 7, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 44, 45, 47, 48 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claims 44, 45, 47, 48 and 50 are indefinite as to “said peptide or polypeptide is selected from the group consisting of peptides or polypeptides comprising the sequences shown in SEQ ID NO:6.....”, or “said mutant is selected from the group consisting of peptides or polypeptides comprising the sequences shown in SEQ ID NO:6 having a mutation”. Note that Markush group (elected from the group consisting of) is cited in the claim, where closed language should be used, however, the claim also recites “peptides or polypeptides comprising the amino acid sequences shown in SEQ ID NO:6....” or “or peptides or polypeptides comprising the sequences shown in SEQ ID NO:6 having a mutation”, which indicates many peptides or mutants are encompassed and is an open language, thus it is not clear what are the metes and bounds of these peptides. Claims 47, 48 and 50 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

In response, applicants indicate the claims have been amended and the claim language clearly sets forth the metes and bounds of the claims (page 4 of the response). The response has been considered, however, the argument is not persuasive regarding the use of “comprising” in the claim where Markush group is cited because it is not clear what are the metes and bounds of these peptides as indicated in the section above. Regarding the position of the residue having mutation in the sequence (claim 45) and the abbreviation cited (claim 50), the argument is persuasive, the rejection is withdrawn.

6. Claim 47 recites the limitation "mutant" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 47 and 50 are also indefinite because the claims are dependent from a cancelled claim, claim 43.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 44 is rejected under 35 U.S.C. 102(b) as anticipated by Hülksen *et al.* (The Journal of Cell Biology 127, 2061-2069 (1994)).

Hülksen *et al.* disclose the cDNA that encode the proteins of several deletion mutants of human β -catenin which lack either carboxyl- or amino-terminal domains or both, or which have truncations within the region of the 13 armadillo-like repeats, and in these mutants a tag of an epitope of human *c-myc* is attached (Fig. 1A), e.g., Δ C-term (residues 696-781 deleted); Δ N-term (residues 1-131 deleted); Δ N/C-term (residues 1-131 and 696-781 deleted); Δ C Δ R11-13 (residues 555-781 deleted); Δ N Δ R1-3 (residues 1-258 deleted); Δ C Δ R8-13 (residues 424-781 deleted); and Δ N Δ R1-7 (residues 1-422 deleted). The reference also indicates the direct interaction of E-cadherin with full size β -catenin and with mutants lacking either carboxyl- or amino-terminal domains or both by showing the two proteins being membrane-associated when the two cDNA were cotransfected, and immunoprecipitation of β -catenin with anti-tag antibodies, and concludes the interaction of β -catenin with E-cadherin is mediated by armadillo-like repeats and not by terminal domains, and multiple rather than single repeat units are involved in the binding (page 2062, right column, last paragraph-page 2064; Figs. 2 and 3; claim 44). Although the reference does not indicate the sequences of armadillo repeats of human β -

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catenin, where SEQ ID NOs: 6, 7, 8, 9, 10, 11 and 12 correspond to arms 3, 4, 5, 6, 7, 8 and 9, respectively (see Table 1 of the specification), the mutants of Δ N-term, Δ C-term and Δ N/C-term, which contain arms 1-13 (Fig. 1A), mediate the interaction of β -catenin with E-cadherin, thus they meet the criteria of the claimed polypeptides comprising SEQ ID NO:6-11 or 12.

8. Claim 44 is rejected under 35 U.S.C. 102(a) as anticipated by Huber *et al.* (Cell 90, 871-882 (September 7, 1997)).

Huber *et al.* disclose the three dimensional structure of the armadillo repeat region of murine β -catenin, designated β -59, and its two 40 and 10 kDa fragments consisting of residues 134-550 and 551-671, and the fragments stay associated under native conditions and bind to E-cadherin cytoplasmic domain, where residues 134-550 contains armadillo repeats R1-R9, and R3 has the same amino acid sequence as SEQ ID NO:6, and R5, R6, R7, R8 and R9 correspond to SEQ ID NOs: 8, 9, 10, 11 and 12, respectively (page 872, left column; Figs. 1 and 4A; claim 44). The 40 kDa fragment (residues 134-550) of β -59, which contains SEQ ID NOs: 6, 8, 9, 10, 11 and 12, meet the criteria of claimed polypeptides comprising SEQ ID NO:6-11 or 12.

Conclusion

9. No claims are allowed.

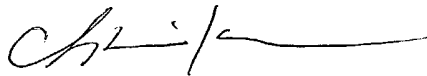
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

A handwritten signature in black ink, appearing to read 'Chih-Min', followed by a long horizontal line.

CMK
November 16, 2004